

8/14



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,989	02/08/2002	Randy Dinkins	028750-219	9928

7590 04/14/2004

Teresa Stanek Rea
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/14

Advisory Action

Application No.

10/067,989

Applicant(s)

DINKINS ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 4/5/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-7, 10-14 and 28-31.

Claim(s) withdrawn from consideration: 8, 9, 15-27, 32 and 33.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE:

New issues:

112, 2nd: Claims 1, 10 and 28 are indefinite in their recitation of "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell". It is unclear what level of hybridization this is, as all nucleic acids will "cross-hybridize" with all other nucleic acids under at least some conditions.

Claims 5, 7, 11, 13, 29 and 31 are indefinite in their recitation of "significant amount of homology to a gene from of Arabidopsis thaliana". It is unclear what gene the exogenous gene has homology to and it is unclear what level of homology is "significant".

New matter: There is no support in the specification for the limitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell".

Continuation of 5. does NOT place the application in condition for allowance because:

112, 1st, enablement: Applicant urges that genes that encode proteins with the same functional activity as the Arabidopsis MinD gene are taught in the specification on pg 7-9. This is not found persuasive; the recited pages of the specification merely provide ranges of identity or hybridization conditions that a homologous gene might have (response pg 10). Sequences of homologous genes are not taught within the full scope of the claims. Applicant urges that although the MinD database was created in October 2002, sufficient information was available to one of skill in the art for identification of proteins with the same functional activity as the Arabidopsis MinD gene, and Fig. 1 shows an alignment of several MinD homologs, showing which amino acids are conserved between species and which are not (response pg 10). This is not found persuasive because the specification does not teach the sequences of homologous genes are not taught within the full scope of the claims; for example, no other plant MinD gene is taught. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at page 1016: "Conception of chemical compound requires that inventor be able to define compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property; thus, when inventor of gene, which is chemical compound albeit complex one, is unable to envision detailed constitution of gene so as to distinguish it from other materials, as well method for obtaining it, conception is not achieved until reduction to practice has occurred, and until after gene has been isolated ... Conception of generalized approach for screening DNA library that might be used to identify and clone erythropoietin gene of then-unknown constitution is not conception of 'purified and isolated DNA sequence' encoding human EPA, since it is not 'definite and permanent idea of the complete and operative invention'." and at pg 1027 "... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them."

112, 1st, written description: Applicant did not address this rejection and it stands for the reasons of record.

112, 2nd: "Exogenous gene": Applicant urges that the claims have been amended to obviate this rejection (response pg 11). This is not found persuasive because whether a particular vector is encompassed by the claims would depend upon the intended use of the vector - a vector comprising the Arabidopsis MinD gene would be encompassed if one intended to use it to transform tobacco, but not if one intended to use it to transform Arabidopsis, even though the vector itself has not changed. The phrase is indefinite because a product must be encompassed by or excluded from the claim under all circumstances. "Same functional activity": Applicant urges that the function of the MinD protein is clearly defined on pg 13 of the specification as "resulting in the production of fewer and larger chloroplasts" (response pg 11-12). This is not found persuasive because several different proteins, when over or under expressed in a plant have this activity, yet they would not be called MinD proteins by other measures of function, for example GTPase activity.

102(a) over Colletti et al: Applicant urges that although Colletti describes vectors comprising an Arabidopsis MinD gene, these vectors are expressed in an Arabidopsis plant cell would cross-hybridize with the homologous gene in the plant cell and Colletti does not describe the limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 13). This is not found persuasive because the recitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Applicant urges that the vectors, plants and methods of Colletti do not inherently disclose a system of increased efficiency; just because a certain result may be present is not sufficient to establish inherency (response pg 13-14). This is not found persuasive because the method steps taught by Colletti are identical to the instantly claimed method steps.

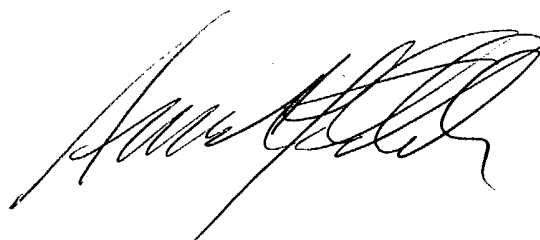
102(a) over Kanamaru et al: Applicant urges that although Kanamaru describes vectors comprising an Arabidopsis MinD gene, these vectors are expressed in an Arabidopsis plant cell would cross-hybridize with the homologous gene in the plant cell and Kanamaru does not describe the limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 13). This is not found persuasive because the

with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim

drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant urges that the vectors, plants and methods of Colletti do not inherently disclose a system of increased efficiency; just because a certain result may be present is not sufficient to establish inherency (response pg 13-14). This is not found persuasive because the method steps taught by Kanamaru are identical to the instantly claimed method steps.

102(b) over Huang et al: Applicant urges that Huang does not describe the claim limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell. This is not found persuasive because the yeast gene would be exogenous to all plants and would not be identical to any plant gene and thus would not "cross-hybridize" to one. Applicant urges that the methods disclosed by Huang do not inherently disclose a system of increased efficiency. This is not found persuasive because the rejection is not applied to any method steps.

Continuation of 10. Other: A complete reply to the final rejection must include cancellation of nonelected claims/deletion of nonelected subjected matter from the examined claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01..



ANNE KUBELIK
PATENT EXAMINER